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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
09/249011	CO ET AL.	
Examiner	Group Art Unit	
GAMBEL	1644	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 7/26/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-63 is/are pending in the application.

Of the above claim(s) 41-45, 47, 48, 51-63 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-40, 46, 49, 50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☑ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

1. Applicant's election of Group I (claims 1-40, 46, 49 ,50) in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 41-45, 47,48, 51-63 have been withdrawn from consideration by the examiner 37 CAR 1.142(b), as being drawn to nonelected invention and/or species

2. Formal drawings and photographs have been submitted which fail to comply with 37 CAR 1.84. Please see the enclosed form PTO-948.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 11-15, 17-23 , 25-27, 29, 31, 34, 37-40: It is apparent that the "3D1" and "H2F", "I2R" antibodies and the "CRL-12524 cell line" are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell lines/hybridomas which produces these antibodies. See 37 CAR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

It is noted that if the claimed and disclosed amino acid sequences or nucleic acid sequences set forth in the instant application encode the entire "3D1", "H2F" and "I2R" antibodies; then a deposit for said "antibodies (cell lines/hybridomas) are not required. The sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin.

6. Claims 5, 11-15, 17-29, 31, 34, 37-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 11-15, 17-23 , 25-27, 29, 31, 34, 37-40 are indefinite in the recitation of "3D1" and "H2F", "I2R" antibodies because their characteristics are not known. The use of ""3D1" and "H2F", "I2R" antibodies" as the sole means of identifying the claimed antibodies renders the claims indefinite because these "names" are merely laboratory designations which do not clearly define the claimed products; since different laboratories may use the same laboratory designations to define completely distinct cell lines or hybridomas.

As pointed out above; the disclosure of the sequence for an entire immunoglobulin satisfies the biological deposit of said immunoglobulin and amending the claims to incorporate the appropriate SEQ ID NOS. would render the claims definite.

B) Claim 5 is indefinite in the recitation of amino acid residue substitutions without a base sequence to indicate the appropriate amino acid residues.

C) Claims 24, 28 are indefinite in the recitation of " stringent conditions" because the metes and bounds of such conditions are ambiguous and unclear and, in turn, the metes and bounds of the claimed "nucleic acids" are not defined.

Applicant is invited to point out a definition for "stringent conditions" in the specification as filed; if one is available.

Also, applicant is invited to consider amending the claims to recite functional language as well.

D) The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 640, 46, 49, 50 are rejected under 35 U.S.C. § 102(e) as being anticipated by Freeman et al.. (U.S. Patent No. 6,084,067) (see entire document). Freeman et al. teach the HF2.3D1 antibody that appears to be same B7-2-specific antibody of the instant application (see columns 27-31, Molecular Probes and columns 69-74, Example 8). In addition, Freeman et al. teaches a variety of art known techniques at the time the invention was made to make humanized or recombinant antibodies to make antibodies less immunogenic for human therapeutic uses (see columns 27-31, Molecular Probes). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations and constructions encompassed by the claims would be inherent properties of the referenced recombinant HF2.3D1-/B7-2-specific antibodies as well as the compositions, nucleic acids, vectors, host cells and methods of making said recombinant HF2.3D1-/B7-2-specific antibodies.

10. Claims 1-40, 46, 49 ,50 are rejected under 35 U.S.C. § 103 as being unpatentable over Freeman et al.. (U.S. Patent No. 6,084,067) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed/admitted on pages 10-29 or Examples I (only indicated as Exemplification on page 35 of the specification/ II/III of the instant specification or as cited by references on the 1449. It would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate chimeric, humanized or recombinant HF2.3D1-/B7-2-specific antibodies, nucleic acids encoding said antibodies, vectors, host cells, methods of making and compositions thereof; given the HF2.3D1 antibody and hybridoma and its associated properties known in the prior art. The instant claims are drawn to HF2.3D1-/B7-2-specific antibodies and fragments thereof and nucleic acids encoding said antibodies, particularly the 3D1/B7-2 specificity.

Freeman et al. teach the HF2.3D1 antibody that appears to be same B7-2-specific antibody of the instant application (see columns 27-31, Molecular Probes and columns 69-74, Example 8). In addition, Freeman et al. teaches a variety of art known techniques at the time the invention was made to make humanized or recombinant antibodies to make antibodies less immunogenic for human therapeutic uses (see columns 27-31, Molecular Probes).

It appears that the instant "3D1" is the same as the "HF2.3D1" B7-2-specific antibody of the prior art.
This reference differs from the instant invention by not disclosing the particular amino acid or nucleic acids of the HF2.3D1/ 3D1 antibody , nor of the particular "H2F", "I2R" antibodies and the "CRL-12524 cell line per se.
However, as clearly taught by Freeman et al.;, it was obvious to one of ordinary skill in the art at the time the invention was made to humanize various antibodies, including "HF2.3D1" B7-2-specific antibody, particularly in view of its specificity and functional properties known at the time the invention was made.

Given the availability of the HF2.3D1/ 3D1 antibody and hybridoma together to others with general immunoglobulin gene cloning and expression strategies, it would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate chimeric or humanized HF2.3D1/ 3D1 antibody B7-2-specific antibodies, nucleic acids encoding said antibodies, vectors, host cells, methods of making and compositions thereof. Given the highly conserved nature of immunoglobulin gene organization and structure and the availability of probes and PCR primers for immunoglobulin gene cloning, one of ordinary skill in the art could have isolated the functionally rearranged heavy and light chain variable regions from the HF2.3D1 hybridoma cell line and determined their sequences with a complete expectation of success. For example, the ordinary artisan does not need to determine the amino acid sequences of a rearranged V (variable) region before cloning. The claims do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected to obtain given the known HF2.3D1 hybridoma thereof, the known heavy and light chain and the art known techniques regarding the production of chimeric antibodies, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement. The claimed DNA sequences must encode a recombinant antibody comprising heavy and/or light chain variable regions of the instant B7-2-specific antibodies.

It is noted Examples 1/II/III of the specification discloses that the design of the instant "3D1", "H2F", "I2R" antibodies and the "CRL-12524 cell line were humanized versions (and associated nucleic acids, vectors, hosts cells) of the "3D1"/B7-2-specific antibody. Furthermore, it is acknowledged that the modifications of "3D1" antibody were designed on known parameters, techniques and computer programs (ABMOD and ENCODE) at the time the invention was made (also see 1449 references), including modifications to the framework regions to allow the recombinant antibodies to maintain substantial affinity to B7-2. Therefore, the claims limitations were expected functional products and modifications of making and preparing humanized HF2.3D1 /B7-2-specific antibodies at the time the invention was made.

Immunoglobulin gene structure and organization were well understood in the art a the time the claimed invention was made and that strategies for cloning the DNAs encoding immunoglobulin variable regions genes were well established in the art at the time the claimed invention was made, as were methods for the production of DNA constructs encoding immunoglobulin variable regions. In addition, it was known at the time the invention was made that the benefits of producing recombinant antibodies to reduce the immunogenicity of therapeutic and diagnostic antibodies in human patients. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and admitted prior art, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

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